

REMARKS

The application has been amended to place it in condition for allowance at the time of the next Official Action.

**Status of Claims**

Claims 45-47 and 49-90 are pending in application. Claims 56 and 58-86 are withdrawn from consideration as being directed to a non-elected species.

Independent claims 45 and 89 are amended to clarify the interaction of the base of the needle and the hollow element. Support for the amendment can be found at least in Figure 1 and on page 12, lines 26-33 of the application as filed.

**35 USC 102 Rejection**

Claims 45 and 89 were rejected under 35 USC 102(b) as being anticipated by HIGGINS 3,110,309. That rejection is respectfully traversed.

Claim 45 recites in part:

1) a longitudinally continuous hollow element forming a reservoir, prefilled with a semi-solid preparation to be injected;

By contrast, HIGGINS discloses a cartridge 10 having a tapered section 19 and an annular recess 20. Both elements 19 and 20 prevent cartridge 10 from being longitudinally continuous.

Claim 45 further recites:

2) a base of a needle supports the needle and directly contacts an entirety of one end face of the hollow element,

so that 3) when the piston comes into direct contact with the base of the needle,

4) an entire dose contained in the reservoir is injected.

By contrast, as seen in Figure 2 of HIGGINS, the end face 17 of cartridge 10 is spaced apart from the base of the needle and in contact with end wall 45 (see column 4, lines 35-50) and instead wall 19 of the cartridge 10 forms a seal with the sleeve 11 (see column 3, lines 11-15).

Moreover, diaphragm 18 prevents direct contact between the piston 33 and the base of the needle.

Further, column 4, lines 46-55 of HIGGINS disclose that a small amount of volume of medicament remains.

Thus, at least based on HIGGINS not meeting features 1)-4) above, HIGGINS does not anticipate claim 45.

Claim 89 recites in part:

1) a hollow reservoir having a continuous longitudinal external surface, prefilled with a semi-solid preparation to be injected. The analysis above regarding claim 45 also applies to HIGGINS as to this feature.

Claim 89 further recites:

2) a needle having a supporting base with a surface that matingly matches with a convex tip (of a piston).

that 3) directly contacting said supporting base when said semi-solid preparation is expelled.

As set forth above, the piston of HIGGINS never comes into direct contact with the base of the needle because the diaphragm 18 prevents such contact. Moreover, even if the ring section 26 of HIGGINS were considered as the base, such ring section is flat and does not matingly match with the convex tip of the piston.

As this reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

### **35 USC 103(a) Rejection**

Claims 45-47, 49-52, 87, 88, 89 and 90 were rejected under 35 USC 103(a) as being unpatentable over YAMASHITA JP 55-073352. That rejection is respectfully traversed.

Claim 45 recites in part:

1) A prefilled syringe configured for the parenteral injection of a semi-solid formulation, comprising:

a longitudinally continuous hollow element forming a reservoir, prefilled with a semi-solid preparation to be injected.

By contrast, YAMASHITA is configured for injecting chemicals or body liquids (see the Derwent abstract) and is not configured to inject a semi-solid formulation. That is, at least based on viewing window 173 (see Figure 1, below), any pressure exerted on the piston in order to expel a semi-solid formulation would crack the glass body 11, since such body would not be sufficiently supported (encased) at the viewing window.

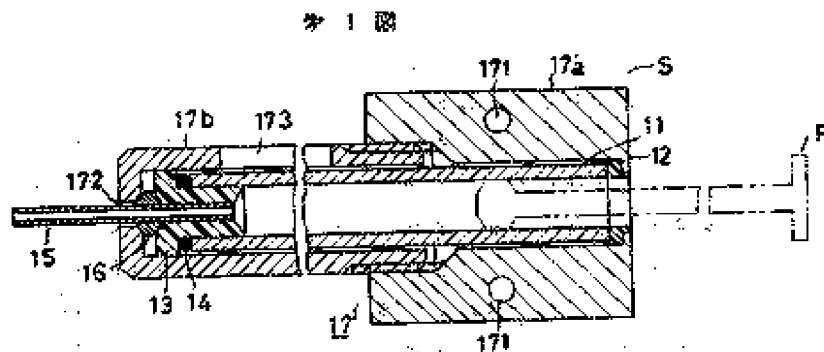
The products injected by YAMASHITA must be in a liquid state and not in a pasty state (semi-solid formulation) as these products are intended to be injected into a living body with which the invention of YAMASHITA is directed. One of ordinary skill in the art of syringes for injecting products, in particularly pasty products, would not have looked to YAMASHITA for a solution to his technical problems in this particular field. That is, Yamashita would not have at first sight given him the solution to his problem, since the configuration of the syringe of Yamashita aims at compensating temperature differences, a problem which is not germane to the present invention and does not provide insight for solving the problems associated with injecting semi-solid formulations.

Moreover, claim 45 recites that a base of the needle comes into direct contact with an entirety of one end face of a hollow element. The position set forth on pages 4 and 5 of the Official Action of June 27, 2008, but not repeated in this Office

Action, is that the side faces of the needle base 13 is edged between the side faces of the hollow element 11.

Based on this position, in YAMASHITA, the side faces of the needle base contact the hollow element. YAMASHITA never discloses that the base of the needle comes into direct contact with an entirety of one end face of the hollow element as required to meet claim 45.

Further, as seen in Figure 1 of YAMASHITA, reproduced below, and as disclosed in the constitution of YAMASHITA, O-ring 14 is between the end face of reservoir 11 and base 13 to account for changes in the cylinder due to expansion and contraction.



As O-ring 14 is between cap 13 and main body 11 and is a necessary element that could not be removed without changing the principle of operation of YAMASHITA, YAMASHITA does not suggest that an entirety of one end face of main body 11 is in direct contact with cap 13. Rather, as set forth above, the O-ring 14 prevents direct contact. Thus, YAMASHITA does not meet claim 45.

Independent claim 89 includes similar features and the analysis above regarding claim 45 also applies to claim 89.

The dependent claims are believed patentable at least for depending from an allowable independent claim.

Claims 53-55 and 57 were rejected as unpatentable over YAMASHITA in view of HIGASHIKAWA 5,704,918. That rejection is respectfully traversed.

HIGASHIKAWA is only cited for the disclosure of an outer casing and two inner tubes that form a reservoir. HIGASHIKAWA does not disclose what is recited in claim 45. As set forth above, YAMASHITA does not disclose what is in claim 45. Since claims 53-55 and 57 depend from claim 45 and further define the invention, the proposed combination of references would not have been sufficient to render obvious claims 53-55 and 57.

#### **Withdrawn Claims**

Since the withdrawn claims depend from claim 45 and thus include all the limitations of claim 45, and since claim 45 is believed allowable, the withdrawn claims should be examined and allowed as part of the present application.

In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance of all claims pending in the application are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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